# Horizontal legislative proposal on data

Information session on ‘one substance, one assessment’ for stakeholders and citizens

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# Obstacles to access and (re-)use of data

Policy evaluations

- Interested parties in chemical safety assessments not always aware of **what** information is available and **where** and **how** to access and use it
- Re-use rights sometimes too **restrictive**
- Shortcomings in interoperability and accessibility of chemical data
- **Different** transparency rules are applied to different assessment steps and data
- Acacemic studies are not sufficiently exploited

# Chemicals Strategy for Sustainability - actions

- Better **streamline** the flow of chemical data between EU and national authorities
- Remove legislative obstacles for the **re-use** of data
- Make data available in appropriate **formats and tools** to ensure interoperability
- Extend the principle of open data and the relevant **transparency** principles from the EU food safety sector to other pieces of chemical legislation
- Enable EU and national authorities to **commission testing and monitoring** of substances as part of the regulatory framework when further information is considered necessary

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See presentation next agenda point

**User** = COM, agencies, MS, industry, citizen with different levels of access

**Common chemical data platform** = de-centralised system providing remote access to existing information systems and data providers

## Occurrence data

IPCHEM

EEA

- Env monitoring (IPCHEM module, LUCAS, WFD, Groundwater Directive)
- Human biomonitoring
- Food and feed
- Residual occurrence data in IPCHEM

*Existing flows possibly to be transferred to EEA if not already there*
*EEA to be more pro-active in connection/collection of MS data*
*EEA to get more powers to ask for data*

## Emissions data

E-PRTR

*Existing flows remain untouched*

## Hazard, exposure, use data

IUCLID

ECHA — REACH, CLP, BPR, POPs

EFSA — PPPR, Food

CPNP? — Cosmetics

Scientific Committees?

*Data to be iuclidised*
*Existing flows remain untouched*

## Health based limit values

*To be developed*

## Academic data

- Guidance on reporting requirements
- Search guide

*To be developed*

## Commissioned studies

- Notification of commissioned studies
- Cfr. food sector
- What information needs to be required?

*To be developed*

## Assessment outcome/(P)ACT

- Assessment outcome + regulatory status
- EUCLEF + (P)ACT

*Existing system to be expanded*

## Analytical tools

- QSAR toolbox
- Exposure models
- Query functions

*Existing tools to be used*

## Control vocabularies

*ECHA's SI activities to be expanded upon*

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# 1. Data dissemination, re-use and transparency

- Data exchange is only possible if data is made **available** and **re-use** of data is allowed

- **Barriers**
  - Technical (cfr formats, vocabularies ~ interoperability)
  - Legal:
    - Horizontal (IPR, sui generis database rights)
    - Specific (regulatory data protection)

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→ Identification of legislative barriers and solutions to overcome them, taking into account free riding, monetary value of data and legacy data

- **Transparency and confidentiality**
  - Different dissemination and transparency rules under different legislations

→ Harmonisation of transparency rules

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# Intellectual property rights

- Copyright ~ Directive 2001/29/EC (Copyrights Directive)
  - Robus studie summaries, applications for autorisation and renewal under REACH could be considered copyrightable
  - No general exception for public authorities. E.g. ECHA cannot re-use copyrightable data on biocidal product authorisation for a REACH application for authorisation, or send it to EFSA for the purpose of approval of a pesticide active substance.

- Sui generis database rights
  - prevents any extraction or re-use of (part of) a database as long as the author has made a substantial investment in either obtaining the contents, its verification or presentation
  - majority of submissions under REACH, CLP, BPR (and by extension other legislation) would potentially fall under this right

→ review of Database Directive planned (unrelated to CSS)

# Regulatory data protection

- E.g. ‘data owner’ under REACH, or BPR
- Does not extend beyond regulatory framework it is implemented in → e.g. protection set out in BPR does not prevent re-use of data under REACH (if data is not copyrightable)

→Use of data to validate/question correctness of information in subsequent submissions?

→No use of data to fill in data gaps in subsequent submissions?

# Confidentiality frameworks

- General framework (Regulation on Access to Documents, Aarhus Convention, General Data Protection Regulation) + legislation-specific confidentiality scheme
- Legislation-specific confidentiality scheme (e.g. Regulation (EU) 2019/1381 (Transparency Regulation))
- Sharing of information between EU bodies, which apply different confidentiality schemes gives rise to a number of legal risks.

→ establish 'originator' principle: obligation for receiving agency to respect confidentiality granted by the supplying agency?

→ or, one centralised database with all scientific information, and database provider/supervisor responsible for assessment for assessing any decision on confidentiality?

# Transparency Regulation

- **Pro-active public disclosure** of all studies/info supporting any request for scientific output by EFSA
- **Intellectual property rights** continue to apply but cannot be used to prohibit public disclosure
- Duly justified **confidential data** are not publicly disclosed
- COM, EFSA and MS have access to full confidential version of submitted request

→Under 1S1A, identification and assessment of options for harmonising transparency rules across legislation based most stringent existing ones

→Take into account **free-riding**, **monetary value of data** and **legacy data**

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# 2. Data generation mechanism

- CSS: *enable EU and national authorities to* ***commission testing and monitoring*** *of substances as part of the regulatory framework when further information is considered necessary*
- Burden of proof remains with industry
- No new information requirements
- 'Data' = measurements, test data, modelling data
- cfr. substance evaluation (REACH), verification tool (Transparency Regulation)

→ Assess overlap with existing mechanisms and additional possibilities of data generation mechanism

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# Use cases

- CLP Regulation – hazard identification, **intrinsic properties**
- REACH – substance evaluation vs/+ authorities generating data themselves
- Information on intrinsic properties of chemicals under **environmental legislation** (not in scope of REACH), e.g. Water Framework Directive (WFD), sewage and drinking water etc.
- High throughput **in vitro screening** to generate mechanistic data
- Environmental **occurrence data** (watch list is limited to WFD purposes)
- Soil biomonitoring, human biomonitoring (**more stability** than projects such as LUCAS, HBM4EU, PARC, …)
- Longe-range transport potential of chemicals under **POPs Regulation**

# Aspects to consider

- Actors
  - COM, MS
- Execution
  - Commercial laboratories, COM (JRC), COM-MS collaboration, experts/consultants, industry (samples)
- Governance
  - One central body (COM or Agency) vs several parties (e.g. EU Agencies)
- Budget/resources
  - COM budget, industry contributions, MS contributions

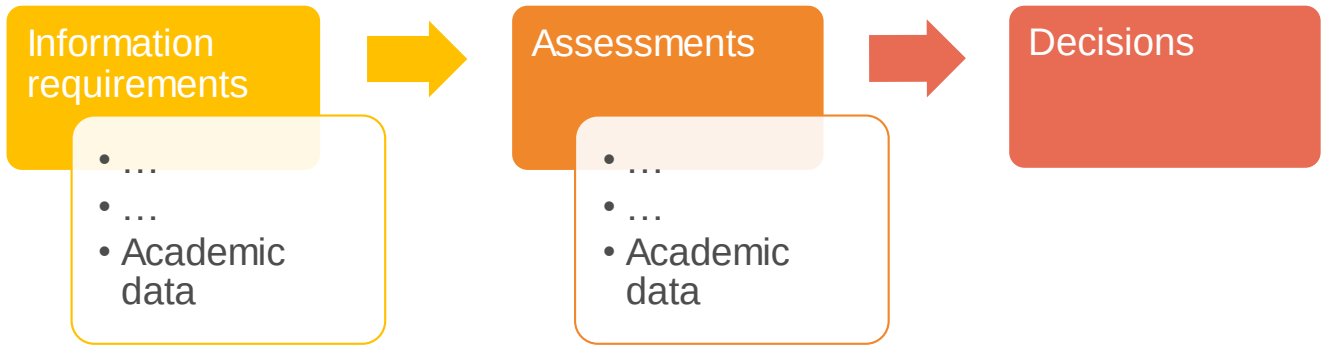
# 3. Notification of studies

- Cfr. Transparency Regulation
  - Business operator commissioning/laboratory being commissioned a study needs to **notify** information to EFSA (name, scope of study, planned start and completion dates)
  - Information is stored in **database** by EFSA
  - Only for studies for regulatory purposes
  - Study taken up in database needs to be taken up in autorisation/approval dossier and vice versa; otherwise, not considered compliant and autorisation/approval will be delayed


→ Similar requirement and mechanism useful/needed for the rest of the chemical sector?

# 4. Academic data

- CSS: *develop tools to improve uptake of academic data*
- Use of academic data in regulatory assessments
  - Published in scientific literature
  - Not carried out specifically to inform regulatory assessments
  - Often using non-standard (non-guideline) experimental (animal and non-animal) or computational methods
  - From traditional to mechanistic data



# Guidance setting minimum quality and reporting requirements

- helps researchers to design, perform and report studies, facilitating regulatory uptake
- broad scope (e.g. in vivo, in vitro, computational modelling, omics etc.)
- entry point for academics to identify requirements
- builds on existing resources
- provides pointers to specific quality documents
- highlights the benefits for the data generators to implement the guidance (developing editorial/funders policy)

# Search guide for finding and retrieving academic data

- implementing the requirements to consider “all available information” in regulatory assessments
- helps assessors to find, access and evaluate academic data from scientific sources
- builds on established tools and practice
- solutions may include:
  - pre-defined search and screening criteria
  - automated solutions, including study repositories and alerts
  - open access platforms, databases in harmonised format
  - policy mechanism to implement it

# 5. Legislative proposal & supporting study

- Horizontal legislative proposal
  - Commission adoption of proposal Q1-Q2 2023
  - Omnibus Regulation amending provisions on data handling and reporting in individual pieces of chemicals legislation

- Supporting study
  - Start May 2022 Mapping of current flows and reporting of data. Identification of options for improvement of inefficiencies.
  - Analysis of possibilities to make data more available to general public
  - Assessment of need and added value of mechanism for data generation and monitoring
  - ~ feasibility study on establishment on open chemical data platform

# Thank you

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